



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 821

[Docket No. FDA-2021-N-0246]

#### Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its medical device regulations to make an editorial nonsubstantive change and replace a reference to an obsolete office with updated information. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993-0002, 301-796-5837.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA's Center for Devices and Radiological Health (CDRH) has reorganized to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs (84 FR 22854, May 20, 2019; 85 FR 18439, April 2, 2020). The newly formed Office of Product Evaluation and Quality (OPEQ) combined the former Office of Compliance, the Office of Device Evaluation, the Office of Surveillance and Biometrics, and the Office of In Vitro Diagnostics and Radiological Health, with a focus on a Total Product Lifecycle (TPLC)

approach to medical device oversight. Within OPEQ there are Offices of Health Technology that focus on the TPLC review of specific types of medical devices as well as cross-cutting offices focusing on specific policy and programmatic needs including the Office of Regulatory Programs and the Office of Clinical Evidence and Analysis. As part of this technical amendment, we are making changes to correct a reference to an obsolete office and to correctly identify the positions with authority to make decisions on exemptions and variances from tracking orders. This change is nonsubstantive and editorial in nature.

## II. Description of the Technical Amendments

The regulations specified in this rule have been revised to make a non-substantive editorial change to correct “Director of the Office of Regulatory Program” to “Director or Principal Deputy Director of the Office of Product Evaluation and Quality” and replace a reference to “Director, Office of Compliance” with “Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality.” The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

## III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). Section 553 of the Administrative Procedure Act (APA) exempts “rules of agency organization, procedure, or practice” from proposed rulemaking (i.e., notice and comment rulemaking) (5 U.S.C. 553(b)(3)(A)). Rules are also exempt when an Agency finds “good cause” that notice and comment rulemaking procedures would be “impracticable, unnecessary, or contrary to the public interest” (5 U.S.C. 553(b)(3)(B)).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA’s revisions make technical or non-substantive changes that pertain solely to the CDRH reorganization and do not alter any

substantive standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

#### List of Subjects in 21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 821 is amended as follows.

#### PART 821--MEDICAL DEVICE TRACKING REQUIREMENTS

1. The authority citation for part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

2. In § 821.2, revise paragraphs (b) introductory text and (c) to read as follows:

§ 821.2 Exemptions and variances.

\* \* \* \* \*

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

\* \* \* \* \*

(c) An exemption or variance is not effective until the Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

Dated: March 25, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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